

10-31-02

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Beth A. BURNSIDE et al.

Serial No.: 09/807,462

Group Art Unit: 1617

Filed: April 11, 2001

Examiner: Alysia Berman

For: ORAL PULSED DOSE DRUG DELIVERY SYSTEM

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Assistant Commissioner for Patents  
Washington, D. C. 20231

Sir:

**CITED MATERIALS**

Applicant(s) hereby disclose the information listed in the attached form PTO-1449.

- ☐ Copies of materials listed but not attached were cited in parent application Serial No. \_\_\_\_\_; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an International Search Report dated \_\_\_\_\_; receipt of the International Search Report and copies of references was confirmed by the PCT International Division of the U.S. PTO in the Notice of Acceptance mailed \_\_\_\_\_.

**ADDITIONAL INFORMATION**

**COMMENTS**

- ☒ The mean plasma profile curve for ADDERALL XR<sup>®</sup>, e.g., an average of about 20 individuals, (as opposed to the individual curve shown in Figure 7 of the specification) is given in the accompanying PDR excerpt. Surprisingly, it is now believed by the inventors that sustained release technology is applicable to amphetamines in that such mean profile is believed attainable by sustained release formulations, contrary to the specification's background section, e.g., at page 1, line 7 to page 2, line 4 from the bottom. A patent application on the unexpected finding has been filed.

**LANGUAGE**

- ☐ All listed materials are in the English language; see 37 C.F.R. § 1.98.
- ☐ Non-English language references:
  - ☐ The reference(s): \_\_\_\_\_ in the English-language is (are) indicated by commercial data bases to correspond to the reference(s): \_\_\_\_\_, respectively.

☐ (An) English-language translation(s) of the references: is (are) provided.

☐ A commercial English-language abstract of reference(s) is (are) provided.

☐ An English-language search report or an equivalent paper from a foreign patent office translated into English in pertinent part in connection with a counterpart foreign application, is provided indicating the relevance of the cited reference(s).

#### FEES

☐ No fee is required for this Information Disclosure Statement because:

☐ This Information Disclosure Statement is being filed within three months of the filing date of a national application (other than a CPA) under § 1.53(d) or within 3 months of the date of entry of the national stage under § 1.491 in an international application;

☐ This Information Disclosure Statement is being filed before the mailing of a first action on the merits;

☐ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that closes prosecution in the application, and is accompanied by a certification below.

☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(i).

☒ A fee is required for this Information Disclosure Statement:

☒ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311 or an action that closes prosecution, and is accompanied by the fee set forth in § 1.17(p).

☐ This Information Disclosure Statement is being filed after the mailing date of a final rejection or a notice of allowance under § 1.311 or an action that closes prosecution, but before the payment of the issue fee, and is accompanied by the fee set forth in § 1.17(p) and a certification below.

#### CERTIFICATION

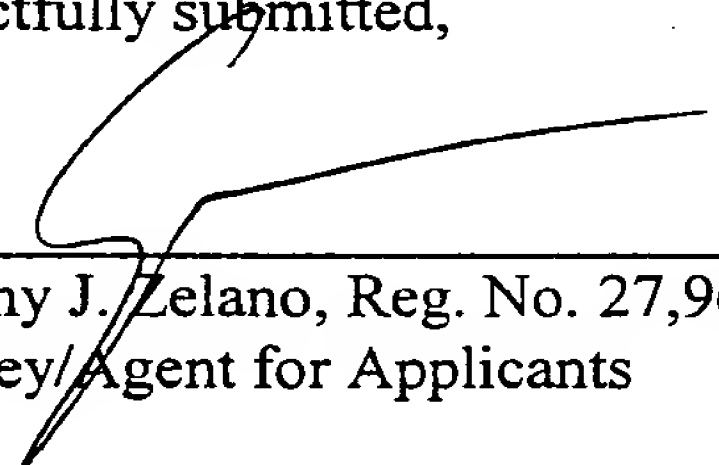
☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, having made reasonable inquiry, no such item was known to any individual designated in 37 CFR § 1.56(c), more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

If a fee is due, attached is a check in the amount of \$ 180. However, the Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
\_\_\_\_\_  
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AJZ:jr